

CLAIMS

1. A *biodegradable* fibre-reinforced *shaped* composite suitable for use as a medical implant which is obtainable by a resin, (co)monomer and/or oligomer reaction injection transfer molding process comprising:
 - 5 providing a shaped fibre preform comprising a presentation of reinforcing fibres in a regular, irregular or profiled fibre distribution in a tool or mould;
 - injecting into *said preform* in said tool or mould a composition comprising (co)monomers and/or oligomers and/or resin of a biodegradable thermoplastic polymer matrix in such a manner as to retain said distribution, orientation and/or fraction, of fibres and composite shape; and
 - 10 (part) polymerising the composition in the mould or tool

wherein *the composite comprises long fibres* (which are up to 10^2 times greater in length than diameter) or long continuous fibres (which are $10^2 - 10^4$ times greater in length than diameter).
2. *Biodegradable* fibre-reinforced *shaped* composite (according to Claim 1) suitable for use as a medical implant comprising matrix and (*long or long continuous*) fibres wherein the matrix and fibres display differential rates of biodegradation as a function of the nature of material or molecular weight thereof *such that in use the matrix and/or fibre biodegrade via an intermediate comprising residual porous matrix or residual fibre form respectively providing voids suitable for primary growth of cells or providing a residual scaffold for attachment and growth of cells.*
3. *Biodegradable* fibre-reinforced *shaped* composite according to claim 1 or 2 wherein the matrix and fibres comprise a combination of materials whereby

a differential degradation rate is exhibited both within and between the matrix and/or fibre.

4. *Biodegradable fibre-reinforced shaped* composite according to Claim 3
5 wherein the matrix is selected from polymers and copolymers of aliphatic polyesters, preferably poly- ϵ -caprolactone.
5. *Biodegradable fibre-reinforced shaped* composite according to any of Claims 1 to 4 wherein the fibre reinforcement is selected from ceramics such as
10 beta-tricalcium phosphate and phosphate free calcium aluminium (Ca-Al), bioglasses such as the glass form of calcium phosphate, calcium metaphosphate (CMP) and calcium sodium metaphosphate (CSM), mixtures of silica, sodium oxide, calcium oxide and phosphorus pentoxide, and polymeric materials as defined in Claim 4.
- 15 6. Process for the producing a *biodegradable fibre-reinforced shaped* composite as hereinbefore defined in any of Claims 1 to 5 comprising providing a shaped fibre preform comprising a presentation of reinforcing fibres in a regular, irregular or profiled fibre distribution in a tool or mould;
injecting into *said preform within* said tool or mould a composition comprising
20 (co)monomers and/or oligomers and/or resin of a biodegradable thermoplastic polymer matrix in such a manner as to retain said distribution, orientation and/or fraction, of fibres and composite shape; and
(part) polymerising the composition in the mould or tool,
characterised in that fibres are long fibres which are up to 10^2 times greater in
25 length than diameter or long continuous fibres which are $10^2 - 10^4$ times greater in length than diameter.

7. *Biodegradable* fibre-reinforced *shaped* composite as defined in any of Claims 1 to 6 which is coated with or associated with or has embedded therein or is impregnated with a selected population of host and/or compatible donor cells, preferably bone derived and/or cartilage derived and/or collagen derived.
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8. *Biodegradable* composite according to Claim 7 comprising primary growth cells selected from bone, cartilage and tissue cells suitable for *providing* a supporting structure of live bone or cartilage or a live vascular structure within the partially *biodegraded* composite, adapted for further growth of remaining
- 10 cells types for total integration as a functioning live system.
9. *Biodegradable* composite according to any of claims 7 and 8 suitable as a surgical implant for reconstruction of bone or cartilage or of soft tissue, muscle characterised by primary degradation *rate of the* matrix or *of the* fibre
- 15 *respectively*.
10. Use of a composite according to any of Claims 1 to 9 for in vivo tissue production by means of impregnation with cells, inductive proteins and therapeutic substances, wherein the composite is then suitable for introduction
- 20 into a living host, *biodegradation and cell growth* and subsequent harvesting the composite in partial or substantially impregnated and/or *biodegraded* state and reimplanting in a locus for reconstructive surgery.
11. Method for the production of a shaped product comprising *providing* a
- 25 mould or tool comprising a 3 dimensional template of a 3 dimensional image of a selected feature or area for implant, *providing* a fibre preform by

introducing fibre into the mould or tool in an effective amount and arrangement, injecting (co)monomers and/or oligomers and/or resin and catalyst and/or initiator and polymerising with subsequent removal of the mould or tool from the shaped product suitable for introduction into a recipient
5 by appropriate means.

12. Method according to Claim 11 wherein the mould or tool is provided by

- 10 (i) medical imaging of a selected feature or area of a patient complementary to or symmetrical with a feature or area to be replaced and/or restructured to obtain data comprising a plurality of co-ordinates defining a three dimensional image;
- (ii) passing data collected from medical imaging to a translating system which interprets said data and generates information for transferring said data
15 to a rapid prototyping system suitable for generating a mould or tool;

and wherein fibre comprises long or continuous fibres providing directional reinforcement.